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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,732	11/01/2001	Leif Andersson	2183-4951US	6509

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,732	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 6/27/2006.

The amendment filed 6/27/2006 is acknowledged and has been entered.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Status of the Claims

Claims 46-48 are currently pending in the application and are addressed herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.

The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In the instant case, claim 46 is drawn to a method comprising the identifying the presence of a paternally imprinted QTL by detecting one or more genetic markers selected from a group comprising genetic markers within the paternally imprinted QTL on chromosome 2 of the pig that represent the actual causal mutation that results in larger muscle mass and/or reduced fat deposit. Therefore, the claims encompass a genus of markers that represent that actual causal mutations that result in larger muscle mass and/or decreased fat deposit. However, upon further consideration, it does not appear that the specification discloses the actual causal mutation that results in larger muscle mass and/or decreased fat deposition. In fact, the specification indicates that the actual causal mutation is still unknown by stating,

> "We have already shown that there is no difference in coding sequence between IGF2 alleles from Pietrain and Large White pigs suggesting that the causative mutations occur in regulatory sequences. An obvious step is to sequence the entire IGF2 gene and its multiple promoters from the three populations. The recent report that a VNTR polymorphism in the promoter region of the insulin (INS) gene affects IGF2 expression suggests that the causative mutations may be at a considerable distance from the IGF2 coding sequence." (See paragraph [0065]; emphasis added).

Furthermore, the actual causal mutation does not appear to be identified in the prior art. It is acknowledged that the specification discloses a marker identified as nt241(G-A) which is a marker that represents a G to A polymorphism in the IGF-2 gene. However, there is no indication that the nt241(G-A) marker (or any other marker disclosed in the specification) represents the actual causal mutation. Accordingly, the specification does not provide adequate

written description of the claimed genus of markers that represent the actual mutation that causes larger muscle mass and/or decreased fat deposit.

Furthermore, claim 47 indicates that the QTL comprises "at least a part of an insulin-like growth factor-2 gene (IGF-2)", and claim 48 indicates that the "at least a part of an insulin-like growth factor-2 gene (IGF-2) and a genetic marker characterized as nt(G-A) or as Swc9". Therefore, claim 47 encompasses a genus of IGF-2 sequences wherein the sequence can comprise any part of any IGF-2 gene (such as any fragment of the IGF-2 gene or a polymorphic or allelic variant of the IGF-2 gene). Similarly, claim 48 encompasses a genus of IGF-2 sequences wherein the sequence can comprise any part of any IGF-2 gene (such as any fragment of the IGF-2 gene or a polymorphic or allelic variant of the IGF-2 gene) wherein the QTL also comprises the marker nt241(G-A) or Swc9. It is noted that the specification indicates that the nt241(G-A) is a marker for a specific polymorphic IGF-2 gene (i.e. an IGF-2 gene having a G to A mutation at nucleotide 241) and that the Swc9 is a maker located in the 3'UTR portion of the IGF-2 gene comprising the nt241(G-A) mutation. As such, claim 47 and 48 encompass a vast number of different IGF-2 sequences, however, the specification discloses only one specific IGF-2 gene sequence of the claimed genus: the IGF-2 gene sequence comprising the nt241(G-A) marker and the Swc9 marker. There is no indication in the specification or the prior art that the QTL associated with larger muscle mass and decreases fat deposit comprises any IGF-2 sequence other than the full length IGF-2 gene sequence comprising the nt241(G-A) and Swc9 markers.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). In the instant case, in the absence of a description of the actual mutation that causes larger muscle mass and/or decreased fat deposit the skilled artisan cannot envision the markers that represent the causal mutation or the IGF-2 sequences encompassed by the claims. Furthermore, in the absence of a description of the IGF-2 sequences other than the IGF-2 gene sequence comprising the nt241(G-A) marker and the Swc9 marker, the skilled artisan cannot envision any IGF-2 gene or fragment thereof which is part of the QTL associated with larger muscle mass and decreased fat deposit other than the specific IGF-2 gene comprising the nt241(G-A) marker and the Swc9 marker. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim 46 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

In the instant case, claim 46 encompasses the genetic marker "S22623". However, a thorough search of the specification was performed and no disclosure of the S22623 marker was found. It is acknowledged that Figures 3A, 3B and 3C disclose marker "Sw2623". It is noted that amending the claim such that S22623 is changed to Sw2623 would obviate this rejection.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 46-48 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for selecting a pig for breeding by identifying a pig having a paternally imprinted quantitative trait locus (QTL) associated with larger muscle mass and decreased fat deposit such that when said pig is used in a breeding program, the offspring of the pig that inherit said QTL from the male parent have larger muscle mass and decreased fat deposit compared to controls, wherein the method for selecting the pig comprises:

identifying the presence of the paternally imprinted QTL associated with larger muscle mass and decreased fat deposit by detecting one or more genetic markers selected from the group consisting of genetic markers linked to the QTL on chromosome 2 of the male pig, genetic markers in linkage disequilibrium with the QTL on chromosome 2 of the male pig, and combinations of any thereof,

wherein the paternally imprinted QTL comprises the insulin-like growth factor-2 gene (IGF-2), as well as the genetic markers Swr2516, nt241(G-A), Swc9, Sw2623 and Swr783 on chromosome 2 of the pig, and

wherein the QTL is present on chromosome 2 of the pig at position 2p1.7,

and wherein the identification of the pig having the paternally imprinted QTL associated with larger muscle mass and decreased fat deposit selects the pig for breeding;

does not reasonably provide enablement for the full scope encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

> *Wands* states on page 1404,
> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The instant claims are drawn to a method for selecting a pig for breeding by selecting a pig which has paternally imprinted QTL associated with larger muscle mass or decreased fat deposit. Regarding the breadth of the claims, the claims encompass identifying a QTL associated with either larger muscle mass OR decreased fat deposit, but not necessarily both. The claims also encompass using genetic markers that represent the actual causal mutation that results in larger muscle mass OR reduced fat deposit. Furthermore, the claims encompass a QTL associated with larger muscle mass and/or decreased fat deposit wherein the QTL comprises any part of an IGF-2 gene, such as any IGF-2 gene polymorphism or any fragment or variant of thereof.

It is acknowledged that the specification discloses that the paternally imprinted QTL is associated with larger muscle mass AND decreased fat deposit (e.g., see page 10 lines 21-22). Furthermore, the data disclosed in the specification appears to indicate that the QTL is associated with both larger muscle mass as well as decreased fat deposit (e.g., see Table 1, Figure 3, etc.). There is no evidence found in the specification or the prior art which indicates that the disclosed QTL can be associated with larger muscle mass independent of fat deposit, or that the QTL can be associated with decreased fat deposit independent of muscle mass, as encompassed by the claims. Since the QTL only appears to be associated with both larger muscle mass and decreased fat deposit, additional experimentation would be required in order to determine if the disclosed paternally imprinted QTL can be associated with either larger muscle mass OR decreased fat deposit without being associated with the other, a finding which would appear to differ from that the disclosed data. Furthermore, a finding that the QTL could associated with either larger muscle mass or decreased fat deposit with being associated with the other would bring into question if the and when the QTL could be associated with both larger muscle mass and decreased fat deposit.

As mentioned above, the claims encompass markers that represents the actual causal mutation which are not adequately described in the specification. Without a clear indication of the marker sequences that represents the actual causal mutation encompassed by the claims, one of skill in the art would not know how to make and/or use the claimed invention without performing an additional experimentation in order to identify said markers. Considering that identification of a specific marker or marker that represents an actual causal mutation of a QTL would require first identifying mutations within the QTL and then performing further

experimentation to determine which mutation(s) are the mutations which cause the traits, the additional experimentation is considered trial and error experimentation where the success of the experimentation is not guaranteed. Therefore, the additional experimentation is not considered routine. Furthermore, the identification of the actual causal mutation would be considered a significant advancement over the state of the art. Therefore, the amount of additional experimentation to identify the genus of markers that represent the actual causal mutation(s) encompassed by the claims is considered undue.

Furthermore, as mentioned above, the claims encompass a QTL associated with larger muscle mass and/or decreased fat deposit wherein the QTL comprises any part of an IGF-2 gene, such as any IGF-2 gene polymorphism or any fragment or variant of thereof. However, neither the specification nor the prior art teach the paternally imprinted QTL associated with increased muscle mass and decreased fat deposit can comprise any IGF-2 gene sequence other than the full length IGF-2 sequence comprising the nt241(G-A) marker and the Swc9 marker. Without a clear indication of the which other IGF-2 sequences are associated with larger muscle mass and/or decreased fat deposit, one of skill in the art would not know how to make and/or use the claimed invention without performing an additional experimentation in order to identify the other IGF-2 sequences. It is noted that the specification indicates that the IGF-2 may be the causative gene responsible for the larger muscle mass/decreased fat deposit in part because of the perfect agreement in map localization (e.g., see page paragraph [0065]). It is noted that experimental data provided (e.g., see Figures 1, 3, etc.) only disclosed one specific IGF-2 gene sequence which is associated with the paternally imprinted QTL: the IGF-2 gene comprising the nt241(G-A) marker and the Swc9 marker. Considering that the specification indicates the IGF-2 gene

comprising the nt241(G-A) marker and the Swc9 and the paternally imprinted QTL associated with larger muscle mass/decreased fat deposit are in perfect agreement in map localization, additional experimentation would be required in order to find other IGF-2 sequences which are also in perfect agreement map localization. The additional experimentation would be trial and error experimentation without a reasonable expectation of identifying another IGF-2 sequence or fragment which is associated with larger muscle mass/decreased fat deposit. Therefore, the additional experimentation is not considered routine. Furthermore, identification that the QTL only requires a part of the IGF-2 gene or an IGF-2 sequence other than the full length IGF-2 sequence comprising the nt241(G-A) and Swc9 markers would be considered a significant advancement over the state of the art. Therefore, the amount of additional experimentation is considered undue.

Response to Arguments

Applicant's arguments filed 6/27/2006 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made for the reasons indicated herein.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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